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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,649	09/04/2003	Yougandh Chitre	A03P1061	8324
36802	7590	11/29/2006	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3766	
DATE MAILED: 11/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,649	CHITRE ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the lead with both a helical tip electrode and a passive fixation structure (claim 12) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. A lead comprising both a helical tip electrode and a passive fixation structure is not disclosed in the original disclosure.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 4 and 6-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 10 of copending Application No. 11/376,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a preformed region adjacent the distal end of a cardiac lead to provide passive fixation is old and well known in the cardiac lead manufacturing arts. Preformed regions such as tines or pre-shaped lead body anchors have long been used to fix the lead to the heart. The examiner took Official Notice to this effect in the previous Office Action. Lacking any arguments to the contrary to effectively traverse the assertion, this feature is now considered admitted prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 4 and 6-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. in view of Helland et al. (Pat. No. 5,545,201).

Regarding claim 1, Thompson et al. do not discuss the use of a helical tip electrode. Helland et al., however, disclose a cardiac lead wherein the active fixation helix is utilized as an electrode to provide bipolar pacing. Those of ordinary skill in the art would have readily recognized the use of a helical electrode to constitute a matter of obvious design. Such configurations are old and commonplace in the art when one desires to ensure good contact with the cardiac tissue. To utilize the fixation helix shown in Fig. 1B of Thompson et al. as an electrode in order to take advantage of the improved electrode/tissue interface contact would have therefore been considered blatantly obvious to anyone of ordinary skill. Related comments apply to claim 18.

Regarding claim 3 and claims with similar limitations, the examiner took Official Notice in the previous Office Action that it was old and well known in the cardiac lead arts to incorporate extendable/retractable helical tips in order to allow for precise anchoring when implanting the lead. The extendable/retractable tip further lessens the chance for tissue damage upon progression of the lead in the vasculature. As the applicants have not effectively traversed this notice, the feature is now considered admitted prior art.

Regarding claim 9, although Thompson et al. are silent as to the exact spacing between a distal extremity of the lead and the defibrillation electrode, the applicants give

no criticality to such spacing. Clearly the spacing depends upon the particular location of the lead within the heart and the various dimensions of the heart itself. Any distance along the lead allowing for effective electrode placement and efficient defibrillation would have been seen as an obvious matter of design to those of ordinary skill in the art looking to best treat the patient.

Limitations of claims not explicitly addressed above are considered clearly addressed by Thompson et al..

Response to Arguments

8. Applicant's arguments filed September 18, 2006 have been fully considered but they are not persuasive.

Lacking an acceptable Terminal Disclaimer or effective arguments, the obviousness-type double patenting rejection must stand.

In reference to the obviousness rejection based on Thompson et al. (Pat. No. 5,899,929) in view of Helland et al. (Pat. No. 5,545,201), the applicants argue that the claimed invention as amended now recites a lead for attenuating T-waves incorporating a helical tip electrode in combination with a ring electrode. It is alleged that Thompson et al. are concerned with the exact opposite issue –namely accurately detecting T-waves. The applicants as a result conclude that Thompson et al. teach away from their invention, stating that there is no motivation to modify the lead of Thompson et al. to attenuate T-waves.

The examiner disagrees. The present claims are directed to a medical electrical lead. The intent of the lead structure is immaterial. If the examiner has found a lead that is structurally equivalent, then the lead must inherently operate in the same manner. The examiner refers the applicants to Fig. 4C of the Thompson et al. reference and Fig. 4 of the present invention. The leads are substantially identical in structure, with the tip electrode area, the ring electrode area, and the interelectrode spacing all falling within the disclosed ranges –ranges specifically taught by the present inventors to be suitable for attenuating T-waves. There is no reason to believe that one lead would operate in the polar opposite manner of the other lead. Other factors may be involved in determining whether the overall system detects or attenuates T-waves (e.g.,

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the type of signal processing structure one desires to connect to the lead). The burden shifts to the applicants to explain why seemingly identical lead structure would result in different modes of operation.

Regarding the use of a helical electrode, it is the examiner's position that those of ordinary skill in the art would have seen the substitution of a distal tip electrode for a distal helical electrode to be a matter of obvious design given that it was old and well-known at the time of the invention to substitute helical fixation devices for tines as a means to secure electrode structure to cardiac tissue (see for example col. 1, lines 14-27 of the '201 patent and/or Figs. 1B and 4C of the '929 patent, and/or par. 0043 of the present invention). Further it was old and well-known to make helical fixation mechanisms electrically active (as discussed by Helland et al.) or passive (as shown by Thompson et al. and of general knowledge in the art) depending on the situation at hand and the condition of the electrode/tissue interface.

It should further be noted that the examiner did not require an election of species to separate the species of Fig. 2 (note Fig. 1B of Thompson et al.), the species of Fig. 3 (note Fig. 4C of Thompson et al.), and the species of Fig. 4 (note Fig. 6 of Helland et al.) from one another because said species were deemed to be patentably indistinct (i.e., if given one species, those of ordinary skill in the art would have considered the other species to be obvious variations).

The applicants' statement of common ownership with regards to Helland '852 is acceptable. The rejection based on this reference has been vacated.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

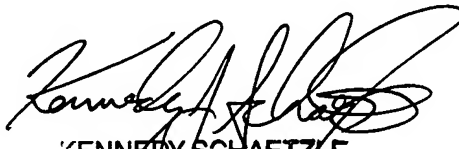
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
November 22, 2006



KENNEDY SCHAETZLE
PRIMARY EXAMINER